IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RICHARD W. COLEMAN and DEMETROS THOMPSON, individually, and as next of kin of and as Co-Administrators of the estate of ELLA MAE COLEMAN
3039 Creel Court
Woodbridge, VA 22192

PLAINTIFFS,

v.

NOVARTIS PHARMACEUTICALS CORPORATION
1 Health Plaza
East Hanover, NJ 07936

DEFENDANT.

JURY DEMANDED

NOW COME plaintiffs Richard W. Coleman and Demetros Thompson, individually, as next of kin of and as Co-Administrators of the estate of Ella Mae Coleman (collectively "Plaintiffs"), by and through counsel, and hereby sue the defendant, Novartis Pharmaceuticals Corporation ("Novartis" or "Defendant"), a Delaware corporation with principal offices located at 1 Health Plaza, East Hanover, New Jersey, 07936-1080 and for their cause of action state:

I. INTRODUCTION

1. The drugs Aredia® and Zometa®, each produced and marketed by Novartis and other related Novartis entities, each cause and precipitate osteonecrosis of the jaw, mandible or maxilla bone among patients taking those drugs. Osteonecrosis is bone death of an area of the bone. Osteonecrosis of the jaw is a permanently disfiguring and extremely painful condition, and can result in the complete loss of the patient's jaw bone. Plaintiff Ella Mae Coleman was infused with Aredia® and Zometa®, and suffered osteonecrosis of the jaw bone.

II. PARTIES

A. PLAINTIFF

1. Decedent, Ella Mae Coleman at all relevant times hereto was a resident of the State of Virginia. Plaintiff Richard W. Coleman is a citizen and resident of the State of Virginia, residing in Woodbridge, Virginia. Plaintiff Demetros Thompson is a citizen and resident of the State of Virginia, residing in Woodbridge, Virginia. Plaintiffs Richard W. Coleman and Demetros Thompson are the duly appointed Co-Administrators of the Estate of Ella Mae Coleman as adjudicated in the Commonwealth of Virginia, Circuit Court of the City of Alexandria. In addition to their own individual interests, Plaintiffs represent the interests of the Estate. The Decedent is survived by her children Stacey Coleman, Anthony Coleman and Plaintiff, Demetros Thompson. Plaintiffs bring this action to recover damages for personal injuries sustained by decedent Ella Mae Coleman after taking Aredia® and Zometa® and for wrongful death.

B. DEFENDANT

2. Defendant Novartis is a Delaware corporation with its corporate headquarters located at 1 Health Plaza, East Hanover, New Jersey, 07936-1080.

3. At all times relevant hereto, Novartis was engaged in the business of marketing, distributing, promoting, testing, labeling and selling Aredia® and Zometa®. Novartis, at present or in the past, markets and distributes Aredia® and Zometa® throughout the world, including all fifty states in the United States, and throughout Virginia.

III. JURISDICTION AND VENUE

4. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by individual Plaintiffs who are citizens of a different state from the Defendant. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1391(c).

IV. FACTUAL BACKGROUND

5. Aredia® and Zometa® are classified as bisphosphonates and are prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. Zometa® is Novartis' "successor" drug to Aredia®, as Aredia® was the first generation version of the drug Zometa®. Zometa® is now marketed by Novartis for all or almost all of the uses for which it previously marketed Aredia®. Aredia® and Zometa® have been approved by the United States Food and Drug Administration.

6. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia®); zoledronic acid or zoledronate (Zometa®); ibandronate (Bondronat®); risedronate sodium (Actonel®); and alendronate (Fosamax®). The non-nitrogenous bisphosphonates include the following: etidronate (Didronel®); clodronate (Bonefos® and Loron®); and tiludronate (Skelid®). Aredia® and Zometa® contain a nitrogen atom, whereas etidronate, clodronate, and tiludronate do not.

7. Studies and medical practices report the frequent and common occurrence of osteonecrosis of the jaw in the users of the nitrogenous bisphosphonates, including Aredia® and Zometa®.

8. Novartis knew or should have known of the disease phosphorus necrosis of the jaw or "phossy jaw," which appeared in the 1800s in persons mining white phosphorus and persons working in white phosphorus match factories. Phossy jaw had been nearly eliminated in the last century through industrial hygiene. The operation of the active ingredients in both Aredia® and Zometa® act and have the same effect as the phosphorus byproducts that caused "phossy jaw." It was foreseeable that any drug with the characteristics of Aredia® and Zometa® would carry the risk of a "phossy jaw"-like reaction.

9. The process by which old bone is taken away and new bone is created is called "remodeling." Both Aredia® and Zometa® were designed specifically to affect the "remodeling" process. Medical science knew, and therefore Novartis knew or should have known, that the jaw operates differently from other bones in the body in that it is subject to unique stresses, and accordingly "remodels" at a far, far greater rate than other bones in the body. Medical science knew, and therefore Novartis knew or should have known, that bisphosphonate drugs had a "site preference" for high remodeling areas, and therefore would have a heightened effect on bones that remodel at a higher rate. Despite this knowledge not one dentist, maxillofacial surgeon, or other jaw or mouth bone specialist was used or assigned to any clinical trial done by Novartis for either Aredia® or Zometa®. This failure constituted a design flaw in every clinical trial and tainted all information provided to the FDA, other regulatory authorities, and peer reviewed journals. Nonetheless, despite any intention of examining the jaw or mouth and without

utilization of any oral specialists in the clinical trials, Novartis's data captured at least six persons who self-reported ONJ-like symptoms in the Zometa® clinical trials. Novartis failed properly to report this to the FDA as part of Novartis's application for approval to market the drug, and further failed to report other adverse event reports to the FDA in a timely manner.

10. Novartis knew and or should have known that bisphosphonates, including Aredia® and Zometa®, inhibit the activity of osteoclasts in the bone. Similarly, Novartis knew or should have known that bisphosphonates cause changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these changes appear to be cumulative in nature.

11. Novartis also knew or should have known that these factors can progress to jaw necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

12. On information and belief, in the year 2002 or before, Novartis was notified by one physician that he had dozens of cases in which patients taking Aredia® had experienced problems so severe that they had lost portions of their jaws. Other oral surgeons during that time frame and before had been reporting such problems to Novartis. On information and belief, Novartis had similar information as to adverse effects caused by its drug Zometa®, which has similar properties and effects as Aredia® and is marketed by Novartis as a more effective replacement for Aredia®. Nevertheless, Novartis did not undertake to advise physicians, notify the consuming public or place information about the possibility of suffering osteonecrosis of the jaw on their products until September of 2004. Novartis did not undertake to notify dental professionals until May of 2005. These efforts to date by Novartis to provide notice are not adequate to provide the public and health care professionals with the information needed to understand the risks inherent in the use of Aredia® and Zometa®, and indeed are themselves false

and misleading.

13. Shortly after Novartis began selling Aredia® and Zometa®, reports of osteonecrosis of the jaw and other dental complications among users further exploded, indicating that Aredia® and Zometa® shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Novartis failed to implement further study of the risk of osteonecrosis of the jaw relative to Zometa® and Aredia®. Rather than evaluating and verifying the safety of Aredia® and Zometa® with respect to osteonecrosis of the jaw, Novartis proposed further uses of Aredia® and Zometa®, notably for osteoporosis under the names Reclast® or Aclasta® or other names, and upon information and belief, urged off-label uses on medical practitioners. Indeed, hundreds of articles have been written by qualified medical professionals and institutions and published in the top medical journals in the world demonstrating that Aredia® causes osteonecrosis of the jaw at a significant rate, and that Zometa® causes osteonecrosis of the jaw at an even higher rate.

14. Rather than warn patients and the medical community, and despite knowledge by Novartis of increased risk of osteonecrosis of the jaw in patients using Aredia® and Zometa®, Novartis continued and continues to defend and aggressively market Aredia® and Zometa®, while downplaying any unfavorable findings and overstating its benefits. This includes attempting to have it approved for use in the treatment of osteoporosis, and in seeking approval to market the drug for osteoporosis changing the name of the drug to "Reclast®" or "Aclasta®" or other names in order to conceal the link between the drug and osteonecrosis of the jaw.

15. Because of the long "half-life" of the drugs Aredia® and Zometa® in the body, the drug remains in the bones of persons who have been infused with it for at least many, many years or even permanently. For this reason, onset of osteonecrosis of the jaw or worsening of a

patient's condition can occur years after infusions of the drug have been discontinued. The label indications that call for an infusion of the drug every three to four weeks in perpetuity constitute an overdose.

16. Despite knowledge of the specific risk, Novartis failed to timely initiate studies to further investigate risks associated with the use of Aredia® and Zometa®.

17. Further, Novartis had a duty to fully test and evaluate Aredia® and Zometa® prior to their introduction to the market, to ensure that the drugs were safe to use for their intended purpose. Novartis failed to satisfy this duty.

18. Upon information and belief Novartis' Safety Reporting System (also known as "STL") generated errors and affected the reporting of safety data to the FDA and negatively impacted clinical trials. To date the system is obsolete and still generating inaccurate safety data that is being submitted to the FDA.

19. Novartis failed properly to conduct "dosing studies" to ascertain the minimum effective quantities of the drugs Aredia® and Zometa®, and thereby to establish the proper quantities of the drugs to be administered to patients and the proper number of infusions which patients should receive. Identifying the minimum effective dosage and setting the dosage instructions accordingly are critical to avoiding the occurrence of side effects. Novartis, to maximize profit, for most or all label indications specified a dosage and dosing schedule of Aredia® and Zometa® far above any indicated for palliative effect. This dosing schedule, for most indications, calls for an infusion of the drug every three to four weeks ***forever***, without any end point or time at which the use of the drug should be discontinued. As a result of Novartis' failure to instruct as to the proper dosage, upon information and belief the amount of the drug

actually administered to Mrs. Coleman constituted an overdose, and contributed to the side effects and harm she suffered.

COUNT I
STRICT LIABILITY

20. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

21. The Defendant was engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising and otherwise distributing Aredia® and Zometa® in interstate commerce, which were sold and distributed throughout the world, including the State of Virginia.

22. Mrs. Coleman was using Aredia® and Zometa® in the manner for which they were intended, or in a reasonably foreseeable manner.

23. Aredia® and Zometa® were expected to and did reach Mrs. Coleman without substantial change in their condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised and otherwise distributed.

24. Mrs. Coleman was not aware of, and reasonably could not have discovered, the actual dangerous nature of Aredia® and Zometa®.

25. Aredia® and Zometa® cause increased risks of osteonecrosis of the jaw upon consumption, and therefore constitutes a product unreasonably dangerous for normal use due to their defective design, defective manufacture, and the Defendant's misrepresentations and inadequate facts disclosed to Mrs. Coleman and her health care providers including, *inter alia*, the actual risk of developing osteonecrosis of the jaw and the permanent, irreversible harm associated with this disease.

26. As a direct and proximate result of Defendant's manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and Zometa® in interstate commerce, Mrs. Coleman suffered from osteonecrosis of the jaw and is entitled to damages enumerated below.

27. The Defendant, therefore, is strictly liable to Ella Mae Coleman. Additionally, Defendant's conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. Plaintiffs are therefore entitled to punitive damages in an amount to be proven at trial.

COUNT II
NEGLIGENCE - NEGLIGENT MANUFACTURE

28. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

29. It was the duty of the Defendant to use reasonable care in the manufacturing, creating, designing, testing, sterilizing, packaging, supplying, and otherwise distributing Aredia® and Zometa®.

30. Contrary to its duty, the Defendant failed: adequately and properly to test and inspect Aredia® and Zometa® so as to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured and sold; adequately and properly to conduct a dosing study or otherwise to test Aredia® and Zometa® to ascertain the minimum effective dosage and to use this information to instruct users of the drug and/or their health care providers of the proper dosage so as to minimize the risk of development of osteonecrosis of jaw or other side effects; to utilize and/or implement a reasonably safe design in the manufacture of Aredia® and Zometa®; to manufacture Aredia® and Zometa® in a reasonably safe condition appropriate

for the use for which they were intended.

31. Defendant manufactured and sold Aredia® and Zometa®, which as constituted were a hazard to Plaintiff's health. Defendant's manufacture and sale of Aredia® and Zometa® as constituted caused Mrs. Coleman to suffer adverse side effects and disease.

32. Defendant was otherwise careless and negligent.

33. As a direct and proximate result of Defendant's negligent, reckless and careless manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and Zometa® in interstate commerce, Mrs. Coleman suffered from osteonecrosis of the jaw and is entitled to punitive damages in an amount to be proven at trial.

COUNT III
NEGLIENCE – FAILURE TO WARN

34. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

35. It was the duty of the Defendant to use reasonable care in the labeling, marketing, selling, advertising, and promoting of Aredia® and Zometa®, and to warn Mrs. Coleman and her medical providers of the true risk of osteonecrosis of the jaw and other side effects when using Defendant's drug.

36. Contrary to its duty, the Defendant failed: adequately and properly to warn Mrs. Coleman of the risks of serious complications and bodily harm when Aredia® and Zometa® is used in the manner for which they were intended; adequately and properly to warn Mrs. Coleman of the risks of diseases when Aredia® and Zometa® is used in a manner for which they were intended; adequately and properly to label Aredia® and Zometa® so as to warn Mrs. Coleman of

the risks of complications and disease; and adequately and properly to label Aredia® and Zometa® so as to warn Mrs. Coleman of the risks of osteonecrosis of the jaw.

37. Further, Defendant failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations. Defendant further failed in the following respects:

a. The labeling lacked adequate information on the use of the drug Aredia® and Zometa® (21 C.F.R. Section 201.56(a) and (d));

b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drug (21 C.F.R. 201.57(e));

c. There was inadequate information for patients for the safe and effective use of Defendant's drug (21 C.F.R 201.57(f)(2));

d. There was inadequate information regarding special care to be exercised by Mrs. Coleman's doctors for safe and effective use of Defendant's drug (21 C.F.R. 201.57(f)(1));

e. The labeling was misleading and promotional (21 C.F.R. 201.56(b)); and

f. Defendant's acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

38. Defendant's products Aredia® and Zometa® were unaccompanied by proper and adequate warnings regarding the risk of osteonecrosis of the jaw associated with the use of Defendant's product and the scope, severity and duration of such injuries.

39. Despite Defendant's failure to provide adequate warnings to protect users or consumers of Aredia® and Zometa®, Defendant nevertheless continued aggressively to market, promote, distribute, and sell the dangerously defective product.

40. As a result of Defendant's negligence and the violations of the statutes and regulations listed above, Mrs. Coleman suffered injuries and damages as alleged herein.

41. As a direct and proximate result of Defendant's failure to warn, Mrs. Coleman developed osteonecrosis of the jaw and is entitled to punitive damages in an amount to be proven at trial.

COUNT IV
BREACH OF EXPRESS WARRANTY

42. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

43. Defendant expressly warranted to Mrs. Coleman, by and through statements made by Defendant or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Aredia® and Zometa® were safe, effective, fit and proper for their intended use.

44. In using Aredia® and Zometa®, Mrs. Coleman and her health care providers relied on the skill, judgment, representations and foregoing express warranties of the Defendant. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

45. As a direct and proximate result of Defendant's breaches of warranties, Mrs. Coleman developed osteonecrosis of the jaw and is entitled to punitive damages in an amount to be proven at trial.

COUNT V
BREACH OF IMPLIED WARRANTY

46. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

47. Prior to the time that Aredia® and Zometa® were used by Mrs. Coleman, Defendant impliedly warranted to Mrs. Coleman that Aredia® and Zometa® were of merchantable quality and safe and fit for the use for which they were intended. Mrs. Coleman was unskilled in the research, design and manufacture of Aredia® and Zometa®, and reasonably relied on the skill, judgment and implied warranty of the Defendant in using Aredia® and Zometa®.

48. Aredia® and Zometa® were neither safe for their intended use nor of merchantable quality, as warranted by Defendant, in that they had dangerous propensities when put to their intended use and would cause severe injuries to the user.

49. As a direct and proximate result of Defendant's breaches of warranties, Mrs. Coleman developed osteonecrosis of the jaw and is entitled to punitive damages in an amount to be proven at trial.

COUNT VI
WRONGFUL DEATH

50. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

51. As a direct and proximate result of Defendant's negligence and otherwise culpable acts described herein, the Decedent, Ella Mae Coleman, consumed Aredia® and Zometa® which caused her to sustain injuries and damages outlined herein and caused her death.

52. Ella Mae Coleman's injuries and death as alleged more fully herein directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and/or misrepresentations.

53. Plaintiff demands judgment of Defendant, Novartis Pharmaceuticals Corporation, for damages in an amount determined by the jury.

WHEREFORE, Plaintiffs pray that this honorable Court enter judgment against Novartis, and in favor of the Plaintiffs, and to award the following relief:

a. For punitive/exemplary damages to the extent necessary and appropriate to punish and deter the conduct complained of herein;

b. For attorneys' fees and costs, plus interest, as allowed by law; and

c. For all other relief that Plaintiffs may be entitled to at equity or at law, including but not limited to further legal and equitable relief as this honorable Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury of this action.

VALAD & VECCHIONE, PLLC

Bart T. Valad, Esq. (DC Bar No. 462814)
John J. Vecchione, Esq. (DC Bar No. 431764)
VALAD AND VECCHIONE, PLLC
3863 Plaza Drive
Fairfax, Virginia 22030
Telephone: (703) 352-4800
Fax: (703) 352-4820

Of Counsel:

Annesley H. DeGaris
CORY, WATSON, CROWDER & DEGARIS, P.C.
2131 Magnolia Avenue, Suite 200
Birmingham, Alabama 35205
Telephone: (205) 328-2200
Facsimile: (205) 324-7896
E-Mail: adegaris@cwcd.com

Attorneys for Plaintiffs

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